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June 22, 2020

VIA ECF

Hon. Theodore D. Chuang
U.S. District Court for the District of Maryland
6500 Cherrywood Lane, Suite 245A
Greenbelt, MD 20770

Re: *American College of Obstetricians and Gynecologists et al. v. U.S. Food and Drug Administration et al.*, No. 8:20-cv-1320-TDC (D. Md.)

Dear Judge Chuang:

Defendants respectfully submit this letter in response to the Court's request during the hearing on Plaintiffs' Motion for Preliminary Injunction (Dkt. No. 11). At the hearing, the Court requested additional information regarding: 1) the drugs for which FDA has exercised enforcement discretion during the COVID-19 pandemic as to the requirement that the drug be dispensed only in certain healthcare settings by or under the supervision of a certified prescriber ("in-person dispensing requirement"); and 2) the involvement of the Secretary of Health and Human Services in the decision to suspend in-person prescribing for certain controlled substances.

A. Other Drug Products Subject to an In-Person Dispensing Requirement

Currently, 17 drug products are subject to a Risk Evaluation and Mitigation Strategy (REMS) with an in-person dispensing and/or administration requirement. For 15 of those drug products, including Mifeprex and its generic, FDA has not stated its intent to exercise enforcement discretion during the pandemic with respect to the in-person dispensing requirement.

As to the remaining two drugs, FDA decided, following requests from the drug sponsors, to exercise enforcement discretion during the pandemic for certain REMS requirements. Those drug products are Spravato (esketamine), a nasal spray treatment for depression, and Tysabri (natalizumab), a drug used in the treatment of multiple sclerosis and Crohn's disease.

On March 23, 2020, FDA notified the sponsor of Spravato that, because patients suspected of having COVID-19 may be self-isolating or quarantined, completion of certain REMS requirements at certified healthcare facilities, including drug administration and patient monitoring, may be difficult during the pandemic. Therefore, FDA informed the drug sponsor that for the duration of the pandemic, FDA does not intend to object to certain healthcare providers supervising the administration of Spravato and monitoring patients post-administration at locations other than certified health care facilities, including at patients' homes. However, FDA requires healthcare providers to supervise administration of the drug and monitor patients post-administration in person.

On April 3, 2020, FDA notified the sponsor of Tysabri that during the pandemic, FDA does not intend to object if Tysabri is dispensed and distributed directly to patients' homes and administered in patients' homes, rather than at a certified healthcare facility. However, FDA permits at-home Tysabri infusions only if given by certain healthcare providers and if certain other conditions are met. Patients cannot self-administer Tysabri infusions.

B. In-Person Prescribing of Controlled Substances

The Court also inquired about the decision to suspend in-person prescribing of certain controlled substances. Defendants respectfully direct the Court's attention to the Drug Enforcement Administration's (DEA) COVID-19 Information Page for further information about this process, which was cited at page 27 of Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction. *See* COVID-19 Information Page, Telemedicine, U.S. Drug Enf't Admin., https://www.deadiversion.usdoj.gov/coronavirus.html#TELE (last visited June 22, 2020) ("COVID-19 Information Page"). The relevant language from DEA's COVID-19 Information Page states:

> While a prescription for a controlled substance issued by means of the Internet (including telemedicine) must generally be predicated on an in-person medical evaluation (21 U.S.C. 829(e)), the Controlled Substances Act contains certain exceptions to this requirement. One such exception occurs when the Secretary of Health and Human Services has declared a public health emergency under 42 U.S.C. 247d (section 319 of the Public Health Service Act), as set forth in 21 U.S.C. 802(54)(D). Secretary Azar declared such a public health emergency with regard to COVID-19 on January 31, 2020.

See id.

After the Secretary declared a public health emergency, section 802(54)(D) of the Controlled Substances Act permitted the practice of telemedicine for "patients located in such areas, and [for] such controlled substances, as the Secretary, with the concurrence of the Attorney General, designates." *See* 21 U.S.C. § 802(54)(D)(ii). On March 16, 2020, the HHS Secretary, with the concurrence of the Acting DEA Administrator, designated that the telemedicine exception in section 802(54)(D) of the Controlled Substances Act applies during the public health emergency to all schedule II-V controlled substances and in all areas of the United States. *See* COVID-19 Information Page.

Defendants thank the Court for its attention to this matter.

Very truly yours,

GUSTAV W. EYLER
Director
Consumer Protection Branch
Civil Division

By: */s/ Hilary K. Perkins*
Hilary K. Perkins
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cc (via CM/ECF):
Counsel of Record

CERTIFICATE OF SERVICE

I certify that on June 22, 2020, I served a copy of this correspondence by filing it with the Court's CM/ECF system, which transmits a copy to all registered parties.

/s/ Hilary K. Perkins
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